

Remarks

This Supplemental Amendment is submitted in view of the interview conducted with the Examiner in the case on August 26, 2008. That interview is also summarized herein.

Status of All of the Claims

Below is the status of the claims in this application.

1. Claim(s) pending: 104, 107, 109-113, 115-117 and 127-132.
2. Claim(s) cancelled: 1-103, 105-106, 108, 114 and 118-126.
3. Claim(s) added: 132-134.
4. Claims withdrawn from consideration but not cancelled: None.

Examiner Interview

Applicant acknowledges and thanks the Examiner for the interview conducted on August 26, 2008. During that interview, the cited prior art was generally discussed, and applicant pointed out that the cited art did not disclose a test strip including a solid, transparent or translucent material, in combination with opaque or colored portions bordering the capillary channel of the test strip, to expose a portion of the capillary channel to be filled in order to use the test strip. The opaque or colored portions distinguish portions of the test strip which do not fill with blood and the user is thereby able to view the movement of a blood sample from an edge, sample application port into the capillary channel and know that the capillary channel has sufficiently filled.

Claim Amendments

Claims 104 and 127 have been amended and claims 132-134 have been added. For the Examiner's convenience, the current amendments to claims 104 and 127 are shown below in tracked changes.

104. (Currently Amended) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

- a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel having opposed sides extending from the sample application port to at least the vent;

- at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface;

- a test reagent adjacent at least the working electrode; and

- visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary channel to accurately perform a test, said visualization means including a solid, transparent or translucent, viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode,

- said visualization means further including said strip body having opaque portions generally aligned with and extending adjacent the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the viewing material and the opaque portions defining a viewing area where the capillary channel is viewable through the solid viewing material, extending from adjacent the sample application port and comprising a portion of the capillary channel required to be filled to have a minimum sample amount for said test strip.

127. (Currently Amended) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

- a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge surface, the capillary channel extending from the sample application port to at least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent;

- at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge surface;

- a test reagent received within the test area of the capillary channel and adjacent at least the working electrode;

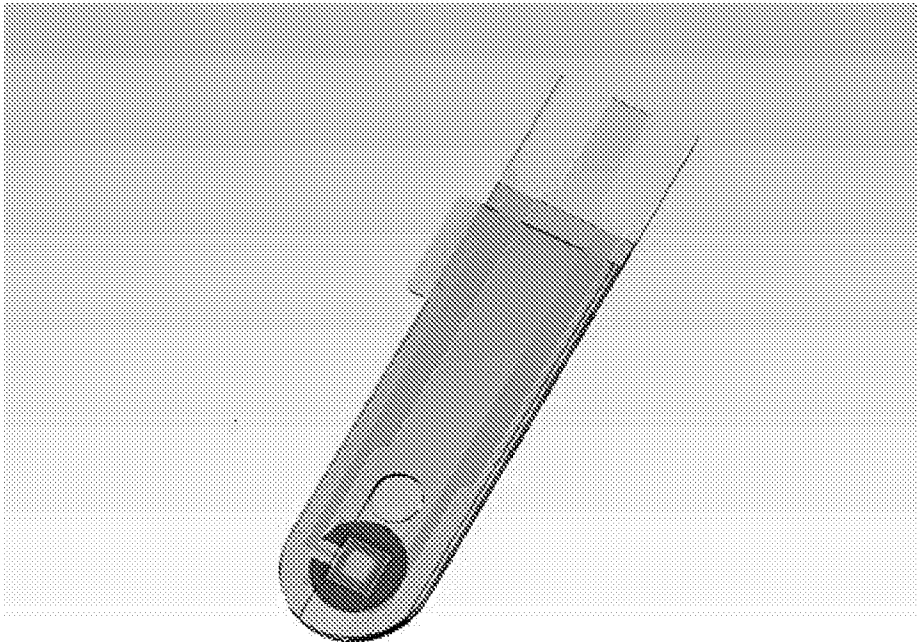
said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area;

said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area extending from adjacent the sample application port continuously up to the working electrode and at least a part of the counter electrode and limited to ~~comprising~~ an area of the capillary channel needed to be filled to conduct an accurate test;

wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.

Comments

The only rejection of the prior-pending claims was based on the prior art device known as Glucometer Elite, marketed by Bayer Corporation and shown below:



As is apparent from the figure, there is nothing in the Glucometer Elite product which provides opaque and/or colored portions which define a viewing area that indicates an area of

the capillary channel which needs to be filled to conduct a test. When blood is dosed to the Glucometer Elite strip, the user is able to see blood enter the strip, but is not able to tell if it is filling the capillary channel or some lesser portion of the interior of the strip.

In contrast, the present invention is directed to a test strip which includes opaque portions specifically located to enable the user to monitor whether sufficient dosing of the test area of the strip has been accomplished. More particularly, the invention provides opaque or colored portions which are positioned adjacent opposite sides of the capillary channel such that only portions of the chamber are viewable in this area.

This feature is contained in all of the pending claims of the application. For example, claim 104 identifies “opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes” and “opaque portions defining a viewing area required to be filled to have a minimum sample amount for said test strip”. Claim 127 requires “opaque portions defining a fill area viewable through the viewing material, the fill area . . . limited to an area of the capillary channel needed to be filled to conduct an accurate test.” Claim 131 includes “colored portions generally aligned with the opposed sides of the capillary channel” and “the viewing material and the colored portions defining a viewing area required to be filled to have a minimum sample amount for said test strip.” Claims 132-134, dependent on claims 104, 127 and 131, respectively, indicate that the viewing or fill areas include only the capillary channel.

These claim limitations clearly distinguish the present invention from the Glucometer Elite test strip, which fails to provide opaque and/or colored portions which define a viewing area or fill area that confirms sufficient filling of the test strip when that area has been filled with the blood sample.

The present invention is therefore seen to be uniquely distinguished from the above-described prior art. Reconsideration of the application and allowance of the pending claims are therefore respectfully requested.

Respectfully submitted,

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